Newborn Screening Quality Assurance Program

Guanidinoacetate Methyltransferase Quality Control Specimen Certification Set 2 – July 2016

Analysis Method: Derivatized – FIA-MS/MS non-kit Material Expiration Date: March 2017

ENRICHMENT LEVELS (endogenous levels not included)

Lot (µmol/L blood)	Guanidinoacetic acid (GAA2)	Creatine (CRE2)
A1512	0	0
B1512	2.5	50
C1512	5.0	150
D1512	7.5	300
E1512	10.0	450

ANALYTICAL INFORMATION

Lot Numbers, Mean Values (\bar{x}), and 95% Confidence Limits (CL). Units are μ mol/L blood.		
Lot	Guanidinoacetic acid (GAA2) Mean/ 95% CL	Creatine (CRE2) Mean/ 95% CL
A1512	$\bar{x} = 3.42$ CL = 2.99 - 3.85	$\bar{x} = 271.82$ CL = 232.29 - 311.35
B1512	$\bar{x} = 5.66$ CL = $4.89 - 6.42$	$\bar{x} = 314.25$ CL = 265.59 - 362.91
C1512	$\bar{x} = 7.80$ CL = $6.65 - 8.96$	$\bar{x} = 398.94$ $CL = 338.02 - 459.86$
D1512	$\bar{x} = 10.60$ CL = $9.13 - 12.06$	$\bar{x} = 573.57$ CL = $486.25 - 660.89$
E1512	$\bar{x} = 12.81$ CL = 11.05 - 14.57	$\bar{x} = 706.31$ $CL = 608.52 - 804.10$

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements. *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*